



**DEPARTMENT OF DEFENSE
FREEDOM OF INFORMATION DIVISION
1155 DEFENSE PENTAGON
WASHINGTON, DC 20301-1155**

Ref: 19-F-1910

SEP 27 2019

Dr. Remington Nevin
MuckRock News
DEPT MR 70910
411A Highland Ave
Somerville, MA 02144-2516

Dear Dr. Nevin:

This is an interim response to your March 24, 2019 Freedom of Information Act (FOIA) request, a copy of which is enclosed for your convenience. We received your request on September 23, 2019, and assigned it case number 19-F-1910. We ask that you use this number when referring to your request.

Although we have already begun processing your request, we will not be able to respond within the FOIA's 20-day statutory time period as there are unusual circumstances which impact our ability to quickly process your request. The FOIA defines unusual circumstances as (a) the need to search for and collect records from a facility geographically separated from this office; (b) the potential volume of records responsive to your request; and (c) the need for consultation with one or more other agencies or DoD components having a substantial interest in either the determination or the subject matter of the records. At least one, if not more of these scenarios applies or would likely apply to your request. While this office handles FOIA requests for the Office of the Secretary of Defense (OSD), the Joint Staff (JS) and other component offices, we do not actually hold their records and our office is not geographically located with these organizations. As we do not hold the records, until the required records searches are complete, we are unable to estimate the potential volume of records or the number of consultations that will be required to make a release determination.

Your request has been placed in our complex processing queue and is being worked based on the order in which the request was received. Our current administrative workload is approximately 2,987 open requests.

In some instances, we have found that requesters who narrow the scope of their requests experience a reduction in the time needed to process their requests.

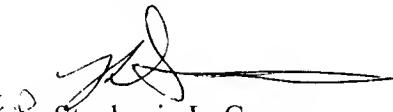
The OSD/JS FOIA Public Liaison, Darrell Williams, is available at 571-3 72-0462 or by email at OSD.FOIALiaison@mail.mil to answer any concerns about the foregoing.

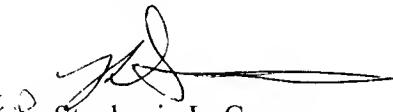
Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road-OGIS
College Park, MD 20740
E-mail: ogis@nara.gov
Telephone: 202-741-5770
Fax: 202-741-5769
Toll-free: 1-877-684-6448

We regret the delay in responding to your request and appreciate your patience. If you have any questions or concerns about the foregoing or about the processing of your request, please do not hesitate to contact Ms. Joan Haynesworth, at joan.l.haynesworth.ctr@mail.mil or 571-372-0428.

Sincerely,



FCR 
Stephanie L. Carr
Chief

Enclosure:
As stated

14-F-1410

From: 70910-5643613@request.muckrock.com
To: DHA FOIA Requests - FOIA Requests
Subject: (No subject) Freedom of Information Act Request: Documents Related to Updating the ASD(HA) DoD Guidance for Malaria Prophylaxis Policy to Include Use of Tafenoquine
Date: Sunday, March 24, 2019 10:50:31 AM
Attachment(s): Tafenoquine.pdf

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Defense Health Agency
FOIA Office
Suite 5101
7700 Arlington Boulevard
Falls Church, Virginia 22042-5101

March 24 2019

DHA Freedom of Information Service Center
7700 Arlington Boulevard, Suite 5101
Falls Church, Virginia 22042-5101
Phone: 1-703-275-6363
Fax: 1-703-275-6363
DHA.FOIA@gmail.com

Re: FOIA Request

To Whom It May Concern:

This is a request under the Freedom of Information Act. I hereby request the following records:

Copies of all correspondence, memorandum, meeting agendas, minutes, and any other documents, related to planned, proposed, or enacted Assistant Secretary of Defense (Health Affairs) policy for the use of tafenoquine, to include any records related to updating the "DoD Guidance for Malaria Prophylaxis" policy, discussed in the Tafenoquine Transition Planning Meeting (enclosed).

The requested documents will be made available to the general public, and thus request is not being made for commercial purposes.

In the event that there are fees, I would be grateful if you would inform me of the total charges in advance of fulfilling my request. I would prefer the request filled electronically, by e-mail attachment if available or CD-ROM if not.

Thank you in advance for your anticipated cooperation in this matter. I look forward to receiving your response to this request within 20 business days, as the statute requires.

Sincerely,

Dr. Remington Nevin

Filed via MuckRock.com
E-mail (Preferred): 70910-56436130@request.muckrock.com
Upload documents directly: Caution: https://www.muckrock.com/accounts/agency_login/defense-health-agency-4190/documents-related-to-updating-the-asd-ha-dod-guidance-for-malaria-prophylaxis-policy-to-include-use-of-tafenoquine-70910?uuid=login_d99fab38-781c-481a-bf0b
b4438c50133).Email - dha.nor.pel.mbx.foia.requests+dmail.mil/agency-reply
Is this email coming to the wrong contact? Something else wrong? Use the above link to let us know.

For mailed responses, please address (see note):

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Somerville, MA 02144-2516

PLEASE NOTE: This request is not filed by a MuckRock staff member, but is being sent through MuckRock by the above in order to better track, share, and manage public records requests. Also note that improperly addressed (i.e., with the requester's name rather than 'MuckRock News' and the department number) requests might be returned as undeliverable.

<Caution: https://email.request.muckrock.com/a/c/w1z1ZCwvAOQNTtV17IAAVN/Ctde1TTDzQFavU/14CNYA_150cm/30F0B853Meheh_hhlyGODEsOiuwtf6e391f07R1hznZTGhW1UNXTG3OGhW1zrZWzPZ83VY1zPw1GzTnV3V11cR2h1h1wz27z1z1>

Arakoda™ (Tafenoquine) Transition Planning Meeting Agenda

(b)(5) 0900-1000 (East Coast Time)

Location: USAMMDA Bldg 1430, (b)(5)

(b)(5)

1. Introductions, Purpose of Working Group

(b)(6)

(b)(6)

(b)(6)

2. Review of Issues

(b)(6)

3. Commercialization Plan

(b)(6)

4. Modification of DOD Guidance for Malaria Prophylaxis

(b)(6)

(b)(6)

5. Inclusion of Arakoda™ onto DOD Peacetime Procurement Vehicles and Contingency Contracts

(b)(6)

6. Inclusion of Arakoda™ onto DOD Formularies

(b)(6)

7. Final Discussion

(b)(5)

MEETING WITH 60P TO DISCUSS TAFENOQUINE COMMERCIALIZATION**PARTICIPANTS:** (b)(6)

(b)(6)

DISCUSSION:

- Priority Review Designation received for TQ; 6 months for FDA review (completed NLT 8 August 2018)
- (b)(4)
- Timeline:

FDA approval	8 August 2018
Tablet validation	(b)(4)
Packaging validation	(b)(4)
Serialization validation	(b)(4)
Validation lots shipped to distributor	(b)(4)
Commercial launch	(b)(4)

- Trade name: (b)(4)
- 100mg tablets
- JPMPG: When are the future quarterly meetings?
- White paper for consultant community?
- Brief at MHSRS (60P brief)
- Who at DoD-HA can guide us as to how to approach them to get the word out?
- (b)(5)
- Can industry reps approach individual MTFs?
- Three (3) validation lots will have (b)(4)
 - Unit of purchase is (b)(4)
 - One Unit of purchase will provide prophylaxis for one service member for 1 month.
 - Unit of purchase cost = (b)(4) (estimate, based on estimated cost of (b)(4) per tablet)
 - Cost of the 3 validation lots is estimated at (b)(4)
 - (b)(6) could we commit to buying this amount to support placebo-controlled studies? Perhaps post-market night vision studies? Tolerability studies?
- Logistics: (b)(4) is the Third Party Logistician (part of (b)(4))
 - They can also do serialization
 - From (b)(4) → Wholesalers (b)(4) etc)
 - (My NOTE: I think (b)(6) reference to wholesalers is the same as what we term as prime vendor distributor)

- Is there a survey that we can generate to gauge potential use?
- Summary of Potential Actions for USAMMDA:
 - Can the Army commit to buying a certain amount of TQ to support post-marketing studies?
 - Can industry reps approach individual MTFs?
 - (b)(4)
 - Who at DoD-HA can we contact reference TQ?
 - When are future JPMPG quarterly meetings?
 - Can we persuade DoD-HA to recommend TQ for malaria treatment?
 - Can we get TQ into the appropriate unit assemblages? Need to engage the USAMMA pharmacist.

(b)(5) (on/about)

IMPROMPTU MEETING WITH (b)(6)

SUBJECT: POTENTIAL COURSES OF ACTION TO FUND PROCUREMENT OF TAFENOQUINE

According to (b)(6), some courses of action:

- (b)(5)
- (b)(5)
- (b)(5)